



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Donald L. Wise, Debra J. Trantolo, David D. Hile and Stephen A. Doherty

Serial No.: 10/613,975

Art Unit: 1642

Filed: July 3, 2003

Examiner: Khatol S. Shahnan Shah

For: *VACCINES TO INDUCE MUCOSAL IMMUNITY*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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An Information Disclosure Statement, including eight (8) pages of Form PTO-1449 was filed in the U.S. Patent and Trademark Office on October 28, 2003. The Examiner has indicated that this Information Disclosure Statement has not yet been received by the U.S. Patent and Trademark Office. Accordingly, Applicants enclose copies of the Information Disclosure Statement, including eight (8) pages of Form PTO-1449, sixty-eight documents cited therein, and the Certificate of Mailing filed on October 28, 2003.

It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

Respectfully submitted,



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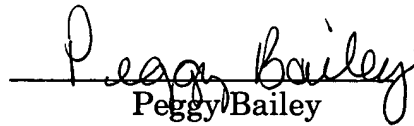
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**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including eight (8) pages of Form PTO-1449 and copies of the sixty-eight documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

**U.S. Patents**

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
5,429,822	07-04-1995	Gresser, et al.	424/426
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### Publications

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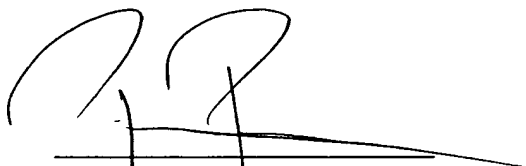
WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," *Immunol. Res.* 16(2): 187-201 (1997).

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**Remarks**

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst  
Reg. No. 31,284

Dated: October 28, 2003

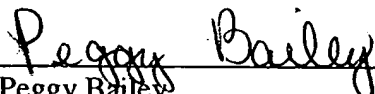
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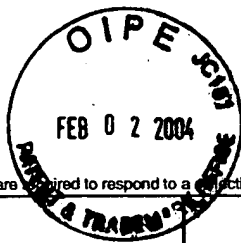
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number

10/613,975

Filing Date

July 3, 2003

First Named Inventor

Donald L. Wise

Group Art Unit

1642

Examiner Name

Attorney Docket Number

CSI 130

Sheet 2 of 8

## OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," <i>Pharm. Res.</i> 10(7): 945-953 (1993).	
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		DENNIS, et al., "Tularemia as a biological weapon," <i>JAMA</i> 285(21): 2763-2773 (2001).	

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Sheet	3	of	8
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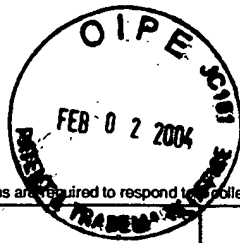
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Sheet	4	of	8	Attorney Docket Number	CSI 130

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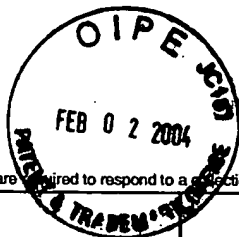
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/613,975
Filing Date	July 3, 2003
First Named Inventor	Donald L. Wise
Group Art Unit	1642
Examiner Name	
Attorney Docket Number	CSI 130

Sheet 5 of 8

### OTHER ART -- NON PATENT LITERATURE DOCUMENTS

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		KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci., USA</i> 89: 10277-10281 (1992).	
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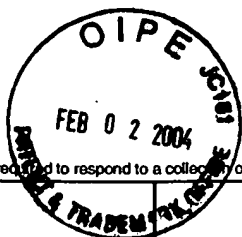
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number

10/613,975

Filing Date

July 3, 2003

First Named Inventor

Donald L. Wise

Group Art Unit

1642

Examiner Name

Attorney Docket Number

CSI 130

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		LUNSFORD, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," <i>J. Drug. Target.</i> 8(1): 39-50 (2000).	
		LUO, et al., "Synthetic DNA delivery systems," <i>Nature Biotech</i> 18: 33-37 (2000).	
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		PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," <i>J. Control. Rel.</i> 75: 211-224 (2001).	

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		Filing Date	July 3, 2003
		First Named Inventor	Donald L. Wise
		Group Art Unit	1642
		Examiner Name	
Sheet 7 of 8	Attorney Docket Number	CSI 130	

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		PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," <i>Vaccine</i> 13(15): 1427-1430 (1995).	
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		STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against <i>Plasmodium falciparum</i> malaria," <i>N. Engl. J. Med.</i> 336: 86-91 (1997).	
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		TINSLEY-BROWN, et al., "Formulation of poly (D,L-lactide-co-glycolic acid) microparticles for rapid plasmid DNA delivery," <i>J. Control. Rel.</i> 66: 229-241 (2000).	
		TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," <i>Proc. 5<sup>th</sup> World Congress, Chem. Eng.</i> (1996).	

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		Filing Date	July 3, 2003		
		First Named Inventor	Donald L. Wise		
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Sheet	8	of	8	Attorney Docket Number	CSI 130

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		VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," <i>J. Biomed. Mat. Res.</i> 19: 349-365 (1985).	
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		WEINER, "Oral tolerance," <i>Proc. Natl. Acad. Sci. USA</i> 91: 10762-10765 (1994).	
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		WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," <i>Immunol. Res.</i> 16(2): 187-201 (1997).	
		YEE, et al., "Loss of either CD4 <sup>+</sup> or CD8 <sup>+</sup> cells does not affect the magnitude of protective immunity to an intracellular pathogen, <i>Fancisella tularensis</i> strain LVS," <i>J. Immunol.</i> 157: 5042-5048 (1996).	

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